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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,772	12/03/2001	Joaquina Faour	PHUS-7	7970
24039	7590	05/25/2004	EXAMINER	
INNOVAR, LLC P O BOX 250647 PLANO, TX 75025			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/004,772

**Applicant(s)**

FAOUR ET AL.

**Examiner**

Lakshmi S Channavajjala

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of amendment and remarks dated 3-24-04 is acknowledged.

Claims 1-55 are pending in this application.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-55 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 1-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 and added independent claims 24-27, 34, 36, 50 and 53 recite the new limitation "and/or" in component c, which is not adequately supported by the instant specification. A careful review of the instant specification, in particular, col. 5 does not reveal support for the polymer coat that could be inert, completely erodible "and/or" water-soluble. The specification only supports a polymer coat that dissolves or erodes (col. 5, lines 44-46) or a microporous material that absorbs water without dissolution of the coat or a substantially completely soluble or completely erodible coat (col. 6, lines 56-57 & 63-66). Thus, the claimed coat can only comprise a polymer that is inert, completely erodible "or" water-soluble, but not inert, completely erodible "and/or" water-soluble.

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### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claim 36 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Similarly, claims 38 and 39, dependent from claim 36, are substantial duplicates of claims 21 23.

Accordingly, claims 38 and 39 are objected.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,613,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims, similar to instant claims, also recite an osmotic device made of an inner drug containing core, a semi permeable membrane surrounding the core, a passage way in the membrane, an inert water soluble or erodible coating surrounding the membrane, which plugs the passage way and a coat external to the erodible coat containing a second drug. The patented claims recite specific drugs in the inner core and external coat, whereas the instant claims are broadly claim first and second active agents. Thus, instant claims are generic and are anticipated by the species in the above patent.

4. Claims 1-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,605,302. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims, similar to instant claims, also recite an osmotic device made of an inner drug containing core, a semi permeable membrane surrounding the core, a passage way in the membrane, an inert water soluble or erodible coating surrounding the membrane and a coat external to the erodible coat containing a second drug. The patented claim 22 further recites that the erodible coat plugs the passageway. The patented claims also recite specific drugs in the inner core and external coat, whereas the instant claims broadly claim first and second active agents. Thus, it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare an osmotic device have a core containing a drug, surrounded by a

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semi permeable membrane, an erodible polymer coat over the membrane and an external coat containing a second active agent, wherein the polymer coat is coated in such a way to plug the passageway because the patent claims encompass both embodiments with and without polymer coat plugging the passageway and still achieve the different release rates for different active agents present in the external coat and inner core.

***Claim Rejections - 35 USC § 103***

5. Claims 24-35 and 40-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,576,604 to Guittard et al (Guittard) in view of US 4,200,098 to Ayer et al (Ayer).

Guittard teaches an osmotic device for delivering a beneficial agent. The device of Guittard comprises a core containing a beneficial agent, a semi permeable membrane surrounding the core, wherein the semi permeable membrane contains a passageway to connect the core to the exterior of the device (col. 5, lines 25-56). The semi permeable membrane is further coated with a lamina (designated as 19 in figure 3 of Guittard) on the exterior surface and is made of a soluble or a disintegrating material. Thus, the device of Guittard containing a core, semi permeable membrane and a lamina over the membrane read on the instant device containing components a, b and c. Further, Guittard teaches that the device may contain a microporous laminate that is in laminar arrangement with the semi permeable membrane, which laminate is further in laminar arrangement with a lamina containing a drug (lines bridging cols. 2-3, col. 6. lines 44-68). Guittard teaches various polymers that are suitable for forming semi permeable membranes, external coat and inert microporous lamina (col. 8-9 and col. 12), which

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include the polymers discussed in the instant specification. Thus, the external lamina containing the drug (of Guittard) provides an immediate release and the drug present inside the core is released upon imbibing the fluid from the external environment into the surrounding medium.

While

Guittard teaches the osmotic drug having features similar to that claimed, Guittard does not specifically state that the coating or lamina surrounding the semi permeable membrane plugs the passageway in the membrane. Thus, the teaching of Guittard can be interpreted in both ways, i.e., the lamina covering the membrane in such a way as to plug the passageway or lamina covering the membrane but without plugging the passageway.

Ayer teaches an osmotic system with a distribution zone for dispensing beneficial medicine comprising a drug core surrounded by a semi permeable membrane, that has a passageway through the membrane, a second wall made of a microporous or a hydrogel material that surrounds the membrane, and an osmotic zone interposed between membrane and the second wall (figure 3 and col. 3). In operation, the external fluid passes through the second wall into the agent present in the zone between wall and membrane. The fluid present in the zone then enters the membrane and enters the core so as to release the drug to the exterior through the passageway (col. 4). Ayer describes the polymers suitable for forming microporous lamina in col. 12, which are similar to the polymers of Guittard and the microporous lamina forming polymers of instant invention. Figure 3 of Ayer clearly shows that the microporous lamina completely covers the semi permeable membrane, including the passageway present in the membrane. Further, Ayer teaches inclusion of a number of active agents in the osmotic device. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention

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to coat the semi permeable membrane of Guittard with a microporous lamina made of an inert soluble polymer in such a way as to completely cover the membrane, including the passageway present in the membrane because Ayer suggests that the microporous wall improves the properties of drug dispensing system of an osmotic device with a semi permeable membrane alone and that by programming the hydrostatic pressure caused by microporous lamina, it is possible to program the drug dispensing rate (col. 7, lines 6 to col. 8, line. Accordingly, one of an ordinary skill in the art would have expected to achieve the desired (same or different) release rates from the core and external coat of the same device by employing a polymer coat that completely envelops the semipermeable membrane, including the passageway therein.

The following rejection of record have been maintained:

***Claim Objections***

6. The amendment filed 3-22-04 proposes amendments to claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. Further, a supplemental oath/declaration should be submitted along with the amendment before allowance, reflecting the above amendment.

37 CFR 1.173(b)(2) relates to the manner of making amendments to the claims in reissue applications. It is not to be used for making amendments to the remainder of the specification or to the drawings. 37 CFR 1.173(b)(2) requires that:

(A) For each claim that is being amended by the amendment being submitted (the current amendment), the entire text of the claim must be presented with markings as defined above.



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(B) For each new claim added to the reissue by the amendment being submitted (the current amendment), the entire text of the added claim must be presented completely underlined;

(C) A patent claim should be canceled by a direction to cancel that claim, there is no need to present the patent claim surrounded by brackets; and

(D) A new claim (previously added in the reissue) should be canceled by a direction to cancel that claim.

ALL AMENDMENTS MUST BE MADE VIS-À-VIS THE ORIGINALLY PATENTED CLAIMS.

*Oath/Declaration*

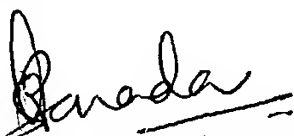
7. The reissue oath/declaration filed with this application is defective (under 37 CFR 1.175 and MPEP 1414) because the oath/declaration filed with this application claims foreign priority, but fails to identify the country of foreign priority, as required by 37 CFR 1.63. A new declaration identifying the country is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala

Examiner

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May 20, 2004